3. (Twice amended) A method for the dehydration of naturally occurring consumable substance, which comprises combining such substance with an ionizable salt, in a concentration of at least 15 % by weight of the substance and an [additional] antimicrobial agent and heating the resulting mixture in particulate form at a temperature below about 110^0 F until the water content is reduced to below 15 %.

15. (Twice Amended) The method of dehydrating chicken cartilage which comprises comminuting such, soaking the resulting product in an aqueous solution of an antimicrobial agent, blending such with potassium or sodium chloride in a concentration of at least 15 % by weight of the comminuted product and dehydrating the resulting mixture in particulate form at temperatures below 110^0 F until the water content is reduced to below 10%.

REMARKS

The claims in the subject application have been further amended to more clearly distinguish the claimed invention over the references cited in the Office Action and overcome the objections raised under 35 USC 112. The claims have been limited to specific minimum concentration of ionizing salt and the description of the nature of the resulting product has been modified to reflect the correct understanding of the Examiner.

As the Examiner correctly sets forth on page 3 of the Action the invention is to maintain the structure of the active ingredients in the product being dehydrated. The need to maintain such structure is illustrated in the Moore patent cited by the Examiner, where in column 3 the inventor explains that in order to maintain the level of activity, any treatment of the product must not destroy the water insoluble structure of the original organic material. The same reasoning is behind the dehydration process of the present invention. Any solution of the product will alter the three-dimensional structure of the

original product since three-dimensional structures are not soluble. It is submitted that the amendments to the claims remove the indefiniteness objection.

Claims 1-16 have been rejected under 35 USC 103(a) as unpatentable over Ericsson et al (US 5,733,241) in view of Moore (US 5, 645,851) or Maret (US 3,878,197).

The Examiner continues to refer to applicants' process as an extraction. It is not. An extraction is defined in chemical dictionaries (e.g., "Condensed Chemical Dictionary", 1966, Reinhold Publishing) as follow:

> "A process in which one or more components are removed from a liquid mixture with a second solvent which itself is nearly insoluble in the first. In other cases the second liquid may dissolve, i.e. extract, from the first liquid the component that is to be purified and leave the associated impurities in the first liquid."

Thus to be an extraction, the process involved must involve the removal of one or more components from the original mixture using an extraction solvent in which the desired material to be extracted is dissolved. The process claimed by applicants does not involve the use of an extraction solvent and does not involve the removal of any components of the mixture by solution in such extraction solvent. Applicants' process is not an extraction process, it a dehydration process in which water is removed by evaporation and not through the use of a solvent. Furthermore no solid components are in any way modified by the dehydration process. In applicants' process the organic substance is treated with aqueous solutions to add components such as the antimicrobial agent and the ionic salt without the removal of any components other than water.

The Ericsson reference discloses an extraction process. Thus the organic substance in Ericsson is treated with an extraction solvent to remove the desired active

components. The Examiner recognizes the fact that Ericsson is an extraction process but fails consider that applicants' process is not. The preferred extracting agents and the only ones exemplified are organic solvents such as ethanol, or other alcohols. Even where the reference suggests the use of an aqueous extracting agent, Ericsson states that the initial organic substance is treated with heating and/or stirring "until the solids are dissolved" (column 4, lines 25, 26). This is the antithesis of applicants' process, which retains the organic substance in its original insoluble state. Any further steps disclosed by Ericsson for the treatment of the extracted material have no significance to applicants' process and it would be improper to impute such steps to applicants' process, which relates to the unextracted product.

The Examiner states that Ericsson macerates the product and distills the product with ethanol. The Examiner's characterization of Ericsson clearly supports applicants' arguments that applicants' process is very different. Applicants' process does not involve the use of a separate solvent, which dissolves part of the product in such solvent, i.e. extracts it, and then recovers the extracted product through distillation.. The Examiner points out that the plant materials yield essential oils. However the Examiner fails to consider that the essential oils are separated from the extracted product before it is submitted to fermentation. The Examiner argues that the Ericsson teaches reducing the moisture content to less than 14 % (column 2). This drying process is performed on the raw product before it is comminuted and before it is exposed to an extraction solvent, which is the actual process claimed in Ericsson. It is a precursor to the extraction process of the reference. This dehydration is done in the absence of an ionizable salt or anti-microbial agent. There is no suggestion for such, on the contrary, the teaching is that

dehydration by itself is adequate t provide stability and thus leads away from applicants' pr cess. That teaching, it is submitted, is inadequate to suggest applicants' process of dehydration, which involves special stabilization steps. Furthermore the temperature range of 100 to 140^{0}F does not suggest an upper limit of 110^0 F and would lead to dehydration which would destroy much of the benefits provided by applicants process.

The Examiner points to the fact that Ericsson in column 4, lines 20 to 51, shows the use of an extracting agent containing NaCl and KCl. It is pointed out that the formulas in the reference do not show a chloride but a carbon iodine compound. It is not clear from the copy submitted to applicants that these formulas are a typographical error. However regardless of whether it is or not, the chlorides are used as part of the extraction solvent and removed with the extracted materials dissolved in the extraction solvent. It is not retained in the original material. In applicants' case the salt becomes part of the product retained after dehydration. No such use is suggested by the reference.

Thus Ericsson discloses an extraction process in which the desired dehydrated product is obtained after solution in a solvent and separation from such solvent.. The dehydration of the unextracted initial raw material shown by Ericsson fails to show or suggest the use of the stabilizers employed by applicants.

Moore discloses drying the product at temperatures below 110^{0}F to preserve the original structure of the protein and its beneficial effect. Even though the drying process used by Moore may be adequate for small quantities of concentrated biologically active materials, it is not suited to large scale production of materials that retain their original structure. In order to achieve such it is necessary to provide stabilizers in the process. Applicants' process of conducting the dehydration in the presence of significant

concentrations f an ionizing salt all ws dehydration on a larg scale without causing the beneficial components of the organic product being dehydrated to change. Thus in th case of collagen II containing materials applicants' process retains the collagen II in its crosslinked, water-insoluble form. Moore adds nothing to the initial drying step disclosed in Ericsson. Neither suggests the use of an ionizing salt to stabilize the dehydration.

The combination of Ericsson with Moore is deemed to be improper since Ericsson is directed to an extraction process involving solution of the active ingredients, whereas Moore teaches that the use of an extraction process destroys the original structure of the collagen II and is therefore undesirable. The rejection of applicants' claims as unpatentable over Ericsson in view of Moore is therefore traversed.

Maret relates to the extraction of components contained in aloe gel after removal of the hulls from the leaves. The desired components of the resulting gel are extracted by reacting the gel with a solution containing citric acid, ascorbic acid glycine and phosphoric acid using ultraviolet light. As disclosed in column 3, lines 1-12, the process involves a stereochemical polymerization of the ingredients contained in the aloe extract catalyzed by UV radiation. Thus, there is a substantial change in the chemical structure of the extract. Any relationship to applicants' process is tenuous at best. The process of the reference is an extraction and not a dehydration. The chemical components of the original organic substance are drastically changed by means of a chemical reaction exactly the thing that applicants' process prevents. The amount of KCl used in the extraction solution is minimal and does not act as a stabilizer for the remaining insoluble

product. Thus Maret adds nothing to the teachings of Ericsson to bring such closer to applicants' claimed inv ntion.

Claims 1-2, 4-6, 8, 12 and 15-17 have been rejected under 35 USC 103(a) as unpatentable over the Japanese abstract JP 359088065 in view of Ueno US 4,789,497

The abstract discloses a process in which comminuted bone and marrow of animals is combined with lecithin and sodium hypochlorite and then further pulverized to an ultra-fine powder under temperature conditions to prevent the thermal denaturation of proteins. The powder is washed and then dehydrated to the "proper water content". By itself the term a "proper water content" is meaningless without a frame of reference. The proper water content could very well mean the water content of the original material. The reference therefore fails to suggest the specific water contents of applicants' claims or that the water content of the original product is reduced. As the Examiner notes the reference fails to disclose the use of an ionizing salt such as is used in the in the thermal dehydration process claimed by applicants. However there are additional differences the Examiner should consider. Thus the reference fails to specify the dehydration process employed. As demonstrated by Ueno dehydration can be accomplished by mechanical means such as filtration, centrifugation or compression. There is no suggestion or disclosure that a thermal dehydration is to be used and of the water content to which the product is to be reduced to.

Ueno relates to dehydrating fish meat using mechanical means to produce a food product and not a concentrated product that contains a high proportion of the beneficial ingredients.. There is no suggestion that the dehydration should be carried out by thermal means or under conditions that prevent denaturization. Thus in the process disclosed by

the reference, significant amounts of aqueous solutions are added to the fish meat and it is clear that the dehydrati n contemplated is the removal of the water of the added solution by mechanical means. As the tables in the references how the products described have water contents of 80% or more which is significantly above the dehydration levels of applicants' process. There further is no suggestion of the use of an antimicrobial agent.

The combination of the Japanese abstract with Ueno fails to suggest the use of a thermal dehydration in the presence of both an antimicrobial agent and an ionizable salt under conditions in which the original structure of the beneficial agents is retained in the dehydrated product.

Although all of applicants' dependent and subsidiary claims are believed to be patentable in view of the foregoing arguments, there are additional reasons why such claims are patentable. Thus claim 2 is deemed to be additionally patentable since none of the references suggests the addition of the ionizing salt in solid form, an important feature considering the low moisture content desired. Claim 3 limits the process to a product containing a water content of less than 15 %. Only Ericsson suggests such a water content but fails to suggest the use of the additives and stabilizers employed by applicants. The combination of Ericsson with Moore to reject applicants' claims based on the dehydration of collagen II-containing proteins (claims 7, 13, 14 and 15-17) is an improper combination since the two references relate to different process methods, i.e., drying versus extraction. The term "animal tissue" furthermore is so broad and all-inclusive as to be inadequate to suggest the collagen II containing materials employed by Moore. Only through applicants disclosure is there a link between the two references as to the nature of the materials involved in the respective processes. It is well established

that the Examiner can not rely on applicants' disclosure as the basis for the combination of references.

Applicants, claims have been demonstrated to be patentable over the art. A Notice of Allowance is respectfully solicited.

Respectfully submitted

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Certificate under 37 CFR 1.8

I hereby certify that a copy of the foregoing Response has been forwarded to Group Art Unit 1616 to the attention Examiner Sharmila S. Gollamudi by facsimile on the date set forth below.

Date: 10/28/02 Signature